K040528
p. 1 of 3

APR 1 5 2004

YAHORNG
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"510(k) Summary"

Submitter's Name:	YA HORNG CO. LTD.
Address:	*No. 35, Zaha Lun, Jon Zsha Village, Antin Shiang, 745, Taiwan, ROC*
Telephone:	886-6-5932201
FAX:	886-6-5935870
Contact Person:	Dr. Jen, Ke-Min
Date Summary Prepared:	2/22/2004
Proprietary Name:	YA HORNG PC COMPATIBLE WRIST BLOOD PRESSURE MONITOR, AK-4000T
Common Name:	BLOOD PRESSURE MONITOR
Classification Name:	NON-INVASIVE BLOOD-PRESSURE MEASUREMENT SYSTEM (per 21CFR section 870.1130)
Device Class:	Class II (performance standards)
Specialty:	CARDIOVASCULAR
Product code:	DXN
Legally Marketed (Predicate) Device :	*AMLUCK AUTOMATIC DIGITAL WRIST BLOOD PRESSURE MONITOR AK-3000 / AK-4000* 510(k) No: K012796

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Description of the new device:

YA HORNG AK-4000T uses the Oscillometric method to measure the blood pressure. The Oscillometric method is adopted clinically to measure the blood pressure recently. It is not needed to use the stethoscope, as in the traditional measuring method, to monitor the Korotkov sound when deciding the systolic or diastolic pressure. The Oscillometric method senses the vibrating signal via the closed air pipe system and utilizes the microcomputer to automatically sense the characteristics of the pulse signal. Through simple calculation, the reading can reflect the accurate real blood pressure, and the systolic pressure is defined as the pressure when the cuff pressure oscillating amplitude begins to increase and the diastolic pressure as the pressure when the cuff pressure oscillating amplitude stops decreasing.

Technological Characteristics of our new device compared to the predicate device:

The technological characteristics of AMLUCK AK-4000T is substantially equivalent to AMLUCK AK-3000 / AK-4000. AMLUCK AK-4000T is of generally the same form and intended to be used in the same manner as the substantially equivalent product; and the new device just add to connect the PC and is passed the relevant EMC and Safety standards. Thus there are substantially equivalent.

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Test Summary:

1. **ELECTRIC SAFETY and EMC test reports,**

General safety	*EN 60601-1:1990+A1+A2+A11+A12+A13*	***PASS***
EMC conformity	*EN 60601-1-2: 1993*	***PASS***

2. **WOVEN COTTON SHEETING**

   Uses the 510K Blood-Pressure Cuff

3. **PERFORMANCE & CLINICAL TEST**
   AAMI / ANSI SP10

YA HORNG Co. Ltd. believes this information and referred document to be sufficient for the FDA to find our proposed device substantially equivalent to the predicate product and other products currently in distribution.

HSU SHENG HSIUNG

Submitter, 2/22/2004
General Maneger
YA HORNG CO., LTD.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 5 2004

Ya Horng Electronic CO., Ltd.
c/o Dr. Jen Ke-Min
ROC Chinese-European Industrial Research Society
No.58, Fu-Chiun St.
Hsin-Chu City
CHINA (TAIWAN) 300

Re: K040528
Trade Name: Ya Horng PC Compatible Wrist Blood Pressure Monitor, AK-4000T
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: February 22, 2004
Received: March 01, 2004

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Lochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

YAHORNG
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Indications for Use

Applicant: YA HORNG CO., LTD.

510(k) Number (if known): **K040528**

Device Name: YA HORNG PC COMPATIBLE WRIST BLOOD PRESSURE MONITOR AK-4000T

- *Indications for use:*

The YA HORNG PC COMPATIBLE WRIST BLOOD PRESSURE MONITOR, Model AK-4000T, is a noninvasive blood pressure measurement system intended to measure the systolic and diastolic blood pressures and pulse rate of an adult individual, over age 18, at home by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to be 5.3" – 8.5".

- *Note:*

Data Transmission: Connection to PC using RS232 cable.

Prescription Use _____ AND/OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Jackner

(Division Sign-Off)
Division of Cardiovascular Devic

510(k) Number K040528

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